IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT BLUEFIELD

DONALD W. PROFFITT, JR., et al.,

Plaintiffs,

v. **CIVIL ACTION NO. 1:17-04391**

BRISTOL-MYERS SQUIBB COMPANY, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the court is defendants' motion for judgment on the pleadings. (Doc. No. 18). For reasons expressed more fully below, that motion is **GRANTED.**

I. Background

This products liability action arises out of plaintiff Donald W. Proffitt, Jr.'s ("Donald") use of the prescription drug Abilify. According to the allegations in the Complaint, which are taken as true for purposes of this motion, Donald suffers from tardive dyskinesia, a condition which results in "restlessness, twitching of the upper and lower extremities, facial tics, jaw clenching and clucking, and constant eye blinking." ECF No. 3-1 at ¶ 7. The Complaint alleges that Donald developed tardive dyskinesia from taking Abilify from August 19, 2014 through July of 2015. See id. at ¶¶ 1 and 5.

On or about November 21, 2017, Donald and his wife, Pamela, filed a four-count complaint against Bristol-Myers Squibb Company

("Bristol-Myers") and Otsuka America Pharmaceutical, Inc. ("Otsuka") in the Circuit Court of Mercer County for their activities "in connection with the[] manufacture, production, labeling, marketing, advertising, sale, promotion and distribution of Abilify." Id. at ¶ 1. Count 1 alleges liability for Negligent Failure to Warn while Count III alleges Strict Products Liability for Failure to Warn. See id. at ¶¶ 16-19 and 25-29. Count II alleges that defendants breached an implied warranty of merchantability due to their "fail[ure] to provide a reasonable warning . . . of the foreseeable risk of the development of tardive dyskinesia associated with the use of Abilify. . . ." Id. at ¶ 24. Count IV is Pamela's claim for loss of consortium. See id. at ¶¶ 30-33.

Defendants seek judgment on the pleadings because, according to them, (1) plaintiffs' state law failure to warn claims are preempted by federal law; (2) plaintiffs have failed to state a claim upon which relief can be granted; and (3) Pamela's loss of consortium claim fails as a matter of law. Plaintiffs disagree.

II. Standard of Review

Federal Rule of Civil Procedure 12(c) provides that, "[a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." Pursuant to Federal Rule of Civil Procedure 12(h)(2)(B), the defense of failure to state a claim upon which

relief can be granted may be raised in a motion for judgment on the pleadings. "A motion for judgment on the pleadings under Rule 12(c) is assessed under the same standards as a motion to dismiss under Rule 12(b)(6)." Occupy Columbia v. Haley, 738 F.3d 107, 115 (4th Cir.2013) (citing Edwards v. City of Goldsboro, 178 F.3d 231, 243 (4th Cir. 1999)).

In evaluating the sufficiency of a pleading, the cases of Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009), provide guidance. When reviewing a motion to dismiss, under Federal Rule of Civil Procedure 12(b)(6), for failure to state a claim upon which relief may be granted, a court must determine whether the factual allegations contained in the complaint "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests," and, when accepted as true, "raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)(quoting Conley v. Gibson, 355 U.S. 41, 47 (1957); 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1216 (3d ed. 2004)). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." Twombly, 550 U.S. at 563. As the Fourth Circuit has explained, "[a] complaint attacked by a Rule 12(b)(6) motion to dismiss will survive if it contains 'enough facts to state a claim to relief that is

plausible on its face.'" Lainer v. Norfolk Southern Corp., 256 F. App'x 629, 632 (4th Cir. 2007) (quoting Twombly, 550 U.S. at 570).

According to Iqbal and the interpretation given it by our appeals court,

> [L]egal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement fail to constitute well-pled facts for Rule 12(b)(6) purposes. See Iqbal, 129 S.Ct. at 1949. We also decline to consider "unwarranted inferences, unreasonable conclusions, or arguments." Wahi v. Charleston Area Med. Ctr., Inc., 562 F.3d 599, 615 n. 26 (4th Cir. 2009); see also Iqbal, 129 S. Ct. at 1951-52.
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> Ultimately, a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Iqbal, 129 S.Ct. at 1949 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). Facial plausibility is established once the factual content of a complaint "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. In other words, the complaint's factual allegations must produce an inference of liability strong enough to nudge the plaintiff's claims "'across the line from conceivable to plausible.'" Id. at 1952 (quoting Twombly, 550 U.S. at 570, 127 S.Ct. 1955).
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> Satisfying this "context-specific" test does not require "detailed factual allegations." Id. at 1949-50 (quotations omitted). The complaint must, however, plead sufficient facts to allow a court, drawing on "judicial experience and common sense," to infer "more than the mere possibility of misconduct." Id. at 1950. Without such "heft," id. at 1947, the plaintiff's claims cannot establish

> a valid entitlement to relief, as facts that are "merely consistent with a defendant's liability," id. at 1949, fail to nudge claims "across the line from conceivable to plausible." Id. at 1951.

Nemet Chevrolet, LTD v. Consumeraffairs.com, Inc., 591 F.3d 250, 255-56 (4th Cir. 2009); see also Iqbal, 556 U.S. at 678 (noting that this standard does not require `detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.") (quoting Twombly, 550 U.S. at 555).

In resolving a motion for judgment on the pleadings, the court must accept all of the non-movant's factual allegations as true and draw all reasonable inferences in its favor. Bradley v. Ramsey, 329 F. Supp. 2d 617, 622 (W.D.N.C. 2004); see also Burback Broadcasting Co. of Delaware v. Elkins Radion Corp., 278 F.3d 401, 406 (4th Cir. 2002) ("Accordingly, [in ruling on a motion pursuant to Rule 12(c),] we assume the facts alleged in the complaint are true and draw all reasonable factual inferences in [non-movant's] favor."). Judgment on the pleadings is appropriate if, taking all of the non-moving party's factual allegations as true, the movant demonstrates that there is no genuine issue of material fact and that movant is entitled to judgment as a matter of law. See Bradley, 329 F. Supp. 2d at 622.

"[W]hen deciding a 12(c) motion, the court may consider `the content of the competing pleadings, exhibits thereto, matters incorporated by reference in the pleadings, [and] whatever is central or integral to the claim for relief or defense.'" In re Coloplast Corp. Pelvic Support Sys. Prod. Liab. Litig., 219 F. Supp. 3d 577, 579 (S.D.W. Va. 2016); see also Farmer v. Wilson Hous. Auth., 393 F. Supp. 2d 384, 386 (E.D.N.C. 2004) (In deciding a motion for judgment on the pleadings, the court "may consider documents incorporated by reference in the pleadings.").

III. Analysis

Plaintiffs' entire lawsuit is grounded in defendants' alleged failure to warn of the dangers of contracting tardive dyskinesia from taking Abilify. However, Abilify's label does and always has warned about the very condition of which plaintiffs complain.[1] Specifically, Abilify's warning label reads in pertient part as follows:

> **5.4 Tardive Dyskinesia**
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> A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated

[1] The court may consider this label without converting the motion to one for summary judgment. See In re Coloplast Corp. Pelvic Support Sys. Prod. Liab. Litig., 219 F. Supp. 3d 577, 579 (S.D.W. Va. 2016) (considering "package insert offer[ing] a product description and a warranty statement" in ruling on motion for judgment on the pleadings); see also Mills v. Bristol-Myers Squibb Co., No. CV 11-968-PHX-FJM, 2011 WL 3566131, *3 n.2 (D. Ariz. Aug. 12, 2011) ("We may consider the Plavix label attached as an exhibit to defendants' motion to dismiss . . . because it is a matter of public record.").

with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.

There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and, thereby, may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, ABILIFY should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that (1) is known to respond to antipsychotic drugs and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient on ABILIFY, drug discontinuation should be considered. However, some patients may require treatment with ABILIFY despite the presence of the syndrome.

ECF No. 18-1 at p.17. Plaintiffs do not even acknowledge that Abilify contains this warning much less allege how it is inadequate. Nor do plaintiffs offer any specifics on what an appropriate warning label would look like.

As one court explained, a failure to warn claim advanced against this backdrop fails to satisfy Twombly and Iqbal.

> [A] failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicating how the provided warnings were inadequate. Bailey v. Janssen Pharmaceutica, Inc., 288 Fed. Appx. 597, 608–09 (11th Cir. 2008) (affirming the dismissal of a failure to warn claim when the complaint "only assert[ed] that the warning was insufficient because it failed to warn of various dangers of the use of [the drug], without explaining either the information available to [the] physician at the time of the administration of the drug or how the contents of the label were inadequate"); Wendell v. Johnson & Johnson, No. C 09–04124, 2010 WL 271423, at *4 (N.D. Cal. Jan. 20, 2010) (dismissing a failure to warn claim because the plaintiffs "fail[ed] to allege how [the] warnings about [the drug] were inadequate"); Mills v. Bristol–Myers Squibb Co., No. CV 11–968, 2011 WL 3566131, at *3 (D. Ariz. Aug. 12, 2011) (dismissing a failure to warn claim because (1) plaintiff did not "plead any facts about what the [drug] label said or how it was deficient;" and (2) "the warning did describe a risk of [the alleged injury]").
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> In contrast with their thorough recitation of Ms. Reed's claimed injuries, plaintiffs plead nothing about the content of Lybrel's warnings. This is likely because, as defendants note by reference to the FDA's website, Lybrel's FDA-approved warning labels warn of the very injuries plaintiffs have pled. Plaintiffs have not contested the authenticity of these FDA warnings despite having had an opportunity to do so. In that regard, the Court takes judicial notice that the warnings advanced by defendants are the FDA-approved warnings for Lybrel. See Kramer v. Time

Warner Inc., 937 F.2d 767, 774 (2d Cir. 1991) (holding district courts may take judicial notice of the contents of certain public records); Muller–Paisner v. TIAA, 289 Fed. Appx. 461, 466, n. 5 (2d Cir. 2008) (holding that judicial notice "may be taken of the defendants' website for the fact of its publication"); Anspach ex rel. Anspach v. City of Philadelphia, Dept. of Public Health, 503 F.3d 256, 273 n.11 (3d Cir. 2007) (taking judicial notice of an FDA publication, "not for the truth of its contents, but rather as evidence of the information provided by the federal government to healthcare providers").

Given all of this, the Reeds fall short of stating a failure to warn claim because the amended complaint does not allege facts identifying how the provided warnings were inadequate. Instead it first alleges (1) "the drug was not accompanied by adequate warnings;" and (2) the drug was promoted "without sufficient disclosure of its dangerous propensities." (Compl. ¶¶ 10, 14.) But assertions that warnings were not "adequate" or "sufficient" are nothing more than legal conclusions unsupported by factual content. The fact gap is never closed. The complaint runs on merely to allege (1) defendants "misrepresent[ed] the risks of the drug to the FDA and/or fail[ed] to inform the FDA of risks inherent in the use of the drug;" and (2) the "warnings and information given to the medical community and women consumers did not accurately reflect the symptoms, duration, scope, or severity of the potential side effects, health concerns, and risks associated with ingesting Lybrel." (Compl. ¶¶ 14, 40.) These additional allegations are simply not "enough to raise a right to relief above the speculative level" since they do not include "enough factual matter (taken as true) to suggest that a [misrepresentation] was made." Twombly, 127 S. Ct at 1965. Pointedly, these allegations do not include any factual content regarding what the misrepresentations were or how the provided warnings and information failed to "accurately reflect" reality; they do not provide a plausible basis to support an inference that Pfizer and Wyeth misrepresented anything. Iqbal, 129 S. Ct. at 1949.

To cut to the chase, the fact (taken here as true) that Ms. Reed suffered from certain conditions that were also identified risks of ingesting Lybrel is tragic, but cannot alone make plausible a claim that

> defendants misrepresented or hid those risks in some way. Plaintiffs have alleged factual content sufficient only to make plausible that Ms. Reed ingested Lybrel and thereafter suffered serious harm. If such allegations were sufficient to state a failure to warn claim, then anyone experiencing harm after using a product where the harm is a warned-of risk could successfully plead a claim. Perversely, the pleaded fact that a warning was given would be the only pleaded fact supporting the claim that a lawfully adequate warning was not given. See Salvio v. Amgen Inc., No. 2:11–cv–00553, 2012 WL 517446, *6 (W.D. Pa. Feb. 15, 2012) (dismissing a failure to warn claim because the "warning provided by Defendants advised Decedent's prescribing physicians of the very injury that occurred"). To allow such a naked claim to go forward would merely green light for plaintiffs an expedition designed to fish for an "in terrorem increment of the settlement value, rather than a reasonably founded hope that the discovery process will reveal relevant evidence." Dura Pharmaceuticals, Inc. v. Broudo, 544 U.S. 336, 347, 125 S. Ct. 1627, 161 L. Ed. 2d 577 (2005) (quoting Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723, 741, 95 S. Ct. 1917, 44 L. Ed. 2d 539 (1975)).
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> Accordingly, the Court finds that plaintiffs have not plausibly pled a failure to warn claim in their amended complaint. Indeed, the facts before the Court are that defendants did warn of the relevant risks. Plausibility requires some factual assertions as to how or why the acknowledged warning was inadequate, that is, about what risk of harm, or in what way, the acknowledged warning failed to warn.

Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 575-77 (E.D.N.Y. 2012); see also Oden v. Boston Scientific Corp., CV 18-0334 (SJF)(SIL), 2018 WL 3102534, *7 (E.D.N.Y. Jun. 4, 2018) ("[T]he Complaint fails to provide facts indentifying how or why the included warnings were inadequate. Although Plaintiff claims that Defendant failed to warn or otherwise provided inadequate warnings of all of the aforementioned risks, the Complaint is

silent as to how the warnings that were indisputably provided, both in Defendant's Instructions for Use as well as the product brochure, were inadequate. . . . Without facts setting forth what the warnings stated and how and/or why the warnings were inadequate, Plaintiff's failure to warn claim is insufficiently pleaded."); Kwasniewsi v. Sanofi-Aventis U.S., LLC, No. 2:12-cv-00515-GMN-NJK, 2013 WL 2558283, *2 (D. Nev. Jun. 8, 2013) (finding plaintiff's "failure to adequately warn" claim inadequately pled because "Plaintiffs' own unsupported conclusion that warnings were insufficient does not satisfy the pleading standard."); Bergstresser v. Bristol-Myers Squibb Co., Civil Action No. 3:12-1464, 2013 WL 1760525, *5 (M.D. Pa. Apr. 24, 2013) (granting defendants' motion for judgment on the pleadings on a negligent failure to warn claim where "[t]he plaintiff d[id] not address the warnings provided on the Abilify label, nor d[id] he point to any deficiencies in the labeling" and where "the plaintiff fail[ed] to indicate what warning should have been given or that any alternative warning would have prevented his physician from prescribing him Abilify"); Mills v. Bristol-Myers Squibb Co., No. CV 11-968-PHX-FJM, 2011 WL 3566131, *3 (D. Ariz. Aug. 12, 2011) ("As for the failure to warn claim, plaintiff must show that the product was defective because it contained an inadequate warning. Plaintiff does ot plead any facts about what

the Plavix label said or how it was deficient. . . . Moreover, the warning did describe a risk of excessive bleeding.").

As the foregoing authorities make clear, plaintiffs' failure to warn claims are inadequately pled because they have failed to address how the Abilify label is inadequate. This is especially true where, as here, the Abilify label warns of the very condition that Donald says he suffers from – tardive dyskinesia.

IV. Conclusion

For the reasons discussed above, the motion for judgment on the pleadings is **GRANTED** based upon plaintiffs' failure to state a claim upon which relief can be granted.[2] Given this ruling, the court does not reach the other grounds advanced by defendants in their motion. The court will delay the entry of a Judgment Order dismissing this case for a period of thirty (30) days in order to allow plaintiffs the opportunity to seek leave of the court to file an amended complaint that addresses the pleading deficiencies outlined herein.

The Clerk is directed to send a copy of this Memorandum Opinion and Order to counsel of record.

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[2] Because the failure to warn claims fail, Pamela cannot recover for loss of consortium. See Horton v. Family Dollar Stores of West Virginia, Inc., Civil Action NO. 2:16-cv-05361, 2017 WL 2312694, *5 (S.D.W. Va. May 26, 2017) (dismissing loss of consortium claim where underlying negligence claim was dismissed). Accordingly, the motion for judgment on the pleadings as to Count IV is **GRANTED**.

IT IS SO ORDERED this 5th day of July, 2018.

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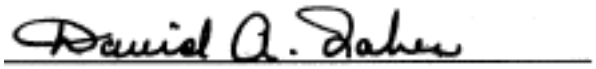

David A. Faber
Senior United States District Judge